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No. 94-372

In the Supreme Court of the United States

OCTOBER TERM, 1994

DONNA E. SHALALA, SECRETARY OF HEALTH AND HUMAN SERVICES, PETITIONER

v.

MARGARET WHITECOTTON, ET AL.

ON WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

REPLY BRIEF FOR THE PETITIONER

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TABLE OF AUTHORITIES

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1. We have argued in our opening brief (Br. 20-29) that the court of appeals erred in holding that the National Childhood Vaccine Injury Act, 42 U.S.C. 300aa-1 *et seq.* (1988 & Supp. IV 1992), creates a presumption that a vaccine has caused a compensabie condition any time that a child has experienced a symptom or manifestation of that condition during the period set forth in the Vaccine Injury Table, even if the condition had already manifested itself prior to administration of the vaccine. Under the text of the Act, to obtain the benefit of a presumption of causation, a claimant must establish either that the child experienced no symptom or manifestation of the condition prior to administration of the vaccine, or that the child had a preexisting condition that

was significantly aggravated after administration of the vaccine. 42 U.S.C. 300aa-11(c)(1)(C)(i). See also American Academy of Pediatrics Amicus Br. 3-9 (discussing text and legislative history of the Act that supports Secretary's position). Because the special master found that Maggie's head size indicated that she had already suffered an encephalopathy before she received her third DPT vaccination and that the seizures that she experienced afterwards did not indicate significant aggravation of that preexisting condition, the special master and the Court of Federal Claims properly concluded that respondents could not rely on the presumption of causation established by Section 300aa-11(c)(1)(C)(i). See Pet. App. 9a-23a, 30a-43a.

Surprisingly, neither respondents nor their amici attempt to defend the interpretation of Section 300aa-11(c)(1)(C)(i) adopted by the court of appeals in reversing the decision of the Court of Federal Claims and ordering the payment of compensation to respondents. Instead, they attempt to defend the result reached by the court of appeals on numerous other grounds. In particular, respondents contend that: (1) the special master erred in concluding that Maggie had a preexisting encephalopathy (Br. 23, 40-41); (2) the special master erred in his analysis of the issue of significant aggravation (Br. 20 & n.23, 25-27); (3) post-vaccine seizures within the statutory period always create a presumption of causation (Br. 9); and (4) principles established under workers' compensation statutes require compensation here (Br. 41-43). For reasons that differ somewhat from those offered by respondents, Amici Dissatisfied Parents Together, *et al.*, argue that Maggie did not suffer from a preexisting encephalopathy (Br. 9-10) and that the special master erred in his significant aggravation analysis (Br. 13).

The court of appeals did not address any of those contentions. Its holding instead was that a claimant may establish a presumption that a vaccine has caused a child's condition under Section 300aa-11(c)(1)(C)(i) even when that condition manifested itself prior to administration of the vaccine and did not markedly worsen afterwards. Pet. App. 5a-9a. That is the issue on which this Court granted certiorari, and that is the issue it should decide. The Court should not attempt to resolve other issues that were not considered below and that may or may not warrant review by this Court in the future.

Should the Court agree with our submission that the court of appeals adopted an erroneous interpretation of Section 300aa-11(c)(1)(C)(i), it should reverse the judgment of the court of appeals and remand for consideration of any other issues that respondents have properly preserved for appeal. Because an understanding of the additional contentions raised by respondents and their amici may assist the Court in resolving the issue on which it granted certiorari, however, we briefly respond to each of those contentions.

a. Respondents contend (Br. 23, 40-41) that the record does not support the special master's finding that Maggie's head size indicated that she had suffered an encephalopathy prior to administration of the vaccine. In their view, Maggie's post-vaccine seizures were therefore the first manifestation of an encephalopathy. The government's expert testified, however, that Maggie's head size at birth indicated that she was born with a serious brain disorder characterized by impairment of cognition and motor activities. J.A. 45-46. One of respondents' two experts agreed that Maggie's head size indicated that she had suffered a pre-vaccine encephalopathy. He testified that "[s]omething was clearly

happening to the child before [the DPT shot]." Pet. App. 33a. In his written report, that expert elaborated that the growth of Maggie's head had fallen below the normal curve, which "implies a post-partum injury to the brain, at or near three months of age." *Id.* at 34a. Yet Maggie did not receive her third DPT vaccination (which respondents claim was the cause of her injury) until she was almost four months of age. *Id.* at 11a. In light of that evidence, the special master reasonably found that "[w]hether the injury occurred prior to birth or thereafter, the preponderance of evidence indicates that Maggie was already encephalopathic prior to August 18, 1975." *Id.* at 34a.[1]

Respondents assert (Br. 41-43) that, because Maggie appeared healthy prior to administration of the vaccine, the special master erred in finding that Maggie suffered from a pre-vaccine encephalopathy. As the special master noted, however, it is relatively common for children who are microcephalic not to have any other manifestations of brain damage until they have matured to the point at which developmental milestones are missed. Pet. App. 37a-38a. For example, cerebral palsy may not become evident until a child is one year of age, and mental retardation may not become evident until much later. *Id.* at 38a. The special master therefore reasonably determined based on Maggie's microcephaly alone that Maggie was encephalopathic prior to administration of the vaccine.

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[1] Under the Act, that factual finding and the other findings to which respondents object could not in any event be set aside on review by the Court of Federal Claims or the court of appeals unless they are "found to be arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 42 U.S.C. 300aa-12(e)(2)(B) (Supp. IV 1992).

Amici Dissatisfied Parents Together contend (Br. 8-10) that a small head size cannot be a symptom of an encephalopathy as that term is defined in the qualifications and aids to interpretation of the Table set forth in 42 U.S.C. 300a-14(b)(3)(A). That contention is also without merit. Section 300aa-14(b)(3)(A) defines encephalopathy as "any significant acquired abnormality of, or injury to, or impairment of function of the brain." 42 U.S.C. 300aa-14(b)(3)(A). As noted above, the government's expert testified that Maggie's head size indicated that Maggie was born with a serious brain disorder characterized by impairment of cognition and motor activities, and respondents' expert testified that Maggie's head size was a manifestation of her having suffered a serious injury to the brain prior to administration of the vaccine. That testimony was more than sufficient to establish that Maggie had a pre-existing encephalopathy as that term is defined in the qualifications and aids to interpretation of the Table.

b. Nor did the special master err in his analysis of the issue of significant aggravation. The Act defines a significant aggravation as "any change for the worse in a preexisting condition which results in markedly greater disability, pain, or illness accompanied by substantial deterioration of health." 42 U.S.C. 300aa-33(4). The special master's findings demonstrate that those statutory criteria were not satisfied in this case. Three findings, in particular, are important. First, the special master found that tests performed on Maggie prior to her release from the hospital showed that her condition had not deteriorated as a result of the seizures. Pet. App. 40a. Second, the special master found that after her release from the hospital, Maggie continued to develop at a "slow but sure" pace. *Id.* at 41a. Finally, the special master found that Maggie's neurological problems

gradually manifested themselves, just as they would in a typical case of a child with preexisting microcephaly. *Id.* at 42a. In these circumstances, the special master reasonably determined that Maggie's seizures were not symptomatic of a significant aggravation of her pre-existing encephalopathy. *Id.* at 42a-43a.

Respondents contend (Br. 25-27) that the special master erred in relying on the test of significant aggravation set forth in *Misasi* v. *Secretary of HHS*, 23 Cl. Ct. 322 (1991). That test requires a court to: "(1) assess the individual's condition prior to administration of the vaccine, *i.e.*; evaluate the nature and extent of the individual's pre-existing condition, (2) assess the individual's current condition after the administration of the vaccine, (3) predict the individual's condition had the vaccine not been administered, and (4) compare the individual's current condition with the predicted condition had the vaccine not been administered." *Id.* at 324. According to respondents, the *Misasi* test improperly requires a claimant to prove actual cause. Although amici do not attack the *Misasi* test as such, they argue (Dissatisfied Parents Together Br. 12-13) that in this case, the special master required respondents to prove actual cause.

The special master did not, however, base his finding of no significant aggravation on respondents' failure to prove actual cause. Rather, he ruled against respondents on their significant aggravation claim because he concluded that "no significant aggravation of Maggie's underlying brain disorder was manifested within three days following the said administration of the DPT vaccine." Pet. App. 43a. Given the special master's findings that Maggie appeared neurologically normal when she left the hospital, that she progressed steadily thereafter, and that her present condition is

typical for a child with congenital brain damage, that conclusion was fully warranted. Maggie's seizures were not symptomatic of either "markedly greater disability, pain, or, illness," or "substantial deterioration of health." 42 U.S.C. 300aa-33(4).

c. Respondents contend (Br. 9) that the court of appeals properly found that Maggie suffered a Table encephalopathy because she suffered seizures within the Table period and an encephalopathy is shown by seizures as a matter of law. That contention is incorrect for two reasons.

First, not every seizure is symptomatic of an encephalopathy. Under the Act, an encephalopathy is defined to mean any "*significant* acquired abnormality of, or injury to, or impairment of function of the brain." 42 U.S.C. 300aa-14(b)(3)(A) (emphasis added). Moreover, the Act uses the terms seizures and convulsions interchangeably, 42 U.S.C. 300aa-14(b)(4), and the definition of encephalopathy in the qualifications and aids to interpretation of the Table states that "[a]mong the frequent manifestations of encephalopathy are * * * changes lasting at least six hours in level of consciousness, with or without convulsions." 42 U.S.C. 300aa-14(b)(3)(A). This statutory reference to the combination of seizures and extended loss of consciousness as a frequent manifestation of an encephalopathy would make no sense if every seizure, no matter how brief, were a symptom of an encephalopathy. Accordingly, the Table does not permit a court to assume that every seizure is a symptom of an encephalopathy. The resolution of that issue must be based on the medical evidence in each case.

Second, under the Act, the relevant inquiry is not whether Maggie's seizures constituted a symptom or manifestation of an encephalopathy. Rather, the rele-

vant inquiry is whether the seizures were the *first* symptom or manifestation of the *onset* or *significant aggravation* of an encephalopathy. See 42 U.S.C. 300aa-11(c)(1)(C)(i). Because Maggie's encephalopathy had already manifested itself prior to administration of the vaccine, and did not markedly worsen afterwards, the seizures Maggie suffered in the Table period did not trigger either of the statutory presumptions of causation.

d. Finally, respondents contend (Br. 41-43, 47-49) that they should prevail based on principles that courts have applied in interpreting workers' compensation laws. Those statutes, however, have different language and purposes. Decisions interpreting workers' compensation statutes therefore do not have a bearing on the proper construction of the Vaccine Act.

The cases upon which respondents rely do not assist them here in any event. Those cases hold that when a claimant proves that work-related trauma and a pre-existing condition together cause a claimant's current condition, compensation for that current condition is appropriate. See *In re Compensation of Aquillon*, 653 P.2d 264, 266-267 (Or. Ct. App. 1982), review denied, 658 P.2d 1162 (Or. 1982); *Reynolds* v. *Ruidoso Racing Ass'n*, 365 P.2d 671, 678 (N. Mex. 1961); *Hoppin* v. *Industrial Comm'n*, 692 P.2d 297, 303-304 (Ariz. Ct. App. 1984); *Silva* v. *New England Group, Maremount Corp.*, 444 A.2d 343, 344-345 (Me. 1982). Here, however, the special master found that neither the vaccine nor the seizures Maggie experienced in the Table period contributed to Maggie's current condition. Pet. App. 42a-43a. The cases relied upon by respondents are therefore inapposite.

2. As we have argued in our opening brief (at 29-34), the court of appeals also erred in holding that the

Secretary could not rely on Maggie's preexisting microcephaly to rebut the presumption of causation that arises when the claimant shows that the first symptom or manifestation of the onset or significant aggravation of an injury or condition occurred within the Table period. Pet. App. 7a-8a. The Vaccine Act permits the Secretary to rely on "factors unrelated" to the vaccine to defeat the claim for compensation in that situation. 42 U.S.C. 300aa-13(a)(1)(B). And while the Act precludes reliance on "idiopathic" factors, 42 U.S.C. 300aa-13(a)(2)(A), Maggie's microcephaly is not idiopathic, since it is a defined preexisting condition that logically eliminates the vaccine as the cause of her condition. See Pet. 17-19.

Amici Dissatisfied Parents defend the court of appeals' reasoning on this point in only the most conclusory terms. See Br. 14-18. Respondents offer no defense of the court's reasoning at all. We therefore rely on our opening brief on that issue. Respondents raise two additional points on the "factors unrelated" issue, however, that warrant a response.

a. First, respondents assert (Br. 19) that the court of appeals rejected the Secretary's reliance on an unrelated factor because it concluded that any connection between Maggie's preexisting microcephaly and her current condition was merely speculative. The court of appeals, however, reached no such conclusion. To the contrary, the court acknowledged that the special master's findings that Maggie was microcephalic prior to administration of the vaccine and that Maggie's current condition is typical for a child with microcephaly demonstrated a logical connection between Maggie's microcephaly and her current condition. Pet. App. 8a.

The court of appeals did refer to the Secretary's defense as speculative. Pet. App. 8a. But the court was

simply using the term "speculative" in the same way as it used the term "idiopathic": to refer to the fact that the government was unable to pinpoint the specific cause of Maggie's preexisting microcephaly. *Ibid.* As we have explained in our opening brief (Br. 30-34), the Vaccine Act does not require that kind of proof. To rebut a prima facie case of causation, the Secretary must show by a preponderance of the evidence that a defined factor unrelated to the vaccine caused a child's condition, 42 U.S.C. 300aa-13(a)(1)(B); the Secretary is not required to identify the cause of the cause of the child's condition. As amicus American Academy of Pediatrics explains (Br. 11), "[m]edical literature is replete with acknowledgements of ignorance and uncertainties by eminent researchers as to the causation of birth defects and perinatal injury," and the court of appeals' holding "that only preexisting conditions with known causes can overcome a petitioner's presumption of eligibility, would have serious implications for the nation's vaccine program." See generally *id.* at 11-14, 17-18.

b. Finally, respondents contend (Br. 9-10, 22, 45) that "factors unrelated" to the vaccine are limited in this case to "toxins, trauma, infection or metabolic disturbance." Since Maggie's microcephaly cannot be traced to one of those four factors, respondents argue, the Secretary failed to establish that a factor unrelated to the vaccine caused Maggie's condition. Respondents' contention is without merit.

Section 300aa-13(a)(2)(B) provides that factors unrelated to the vaccine "may * * * include infection, toxins, trauma (including birth trauma and related anoxia), or metabolic disturbances which have no known relation to the vaccine involved, but which in the particular case are shown to have been the agent or agents principally responsible for causing the petitioner's illness, disability, injury, condition, or death." 42 U.S.C. 300aa-13(a)(2)(B). The use of the words "may include" rather than "means" shows that Congress intended the four identified factors to be treated as examples of permissible rebuttal, rather than as an exhaustive list. *Pfizer, Inc.* v. *India*, 434 U.S. 308, 312 n.9 (1978); *United States* v. *New York Telephone*, 434 U.S. 159, 169 & n.15 (1977); *Federal Land Bank* v. *Bismarck Lumber Co.*, 314 U.S. 95, 99-100 (1941).

Respondents concede that point, but then contend (Br. 9-10) that the permissive language of that provision is overridden by Section 300aa-14(b)(3)(B), which relates to encephalopathies. That section provides that "[i]f * * * an encephalopathy was caused by infection, toxins, trauma, or metabolic disturbances the encephalopathy shall not be considered to be a condition set forth in the table." 42 U.S.C. 300aa-14(b)(3)(B). Nothing in that language compels the conclusion that the four listed factors were intended to be the *only* factors that could defeat a claim for compensation when the petitioner relies on the Table and alleges that the child suffers from an encephalopathy.

The second sentence of Section 300aa-14(b)(3)(B) reinforces the conclusion that the first sentence was not intended to limit the Secretary's rebuttal to the four factors it lists, and thereby to render Section 300aa-13(a)(1)(B) of no effect in cases of alleged encephalopathy. The second sentence provides that "[i]f at the time a judgment is entered * * * it is not possible to determine the cause, by a preponderance of the evidence, of an encephalopathy, the encephalopathy shall be considered to be a condition set forth in the table." If respondents' construction of the first sentence were correct, the second sentence would have provided that "if an encephalopathy is not shown by a preponderance of

the evidence to have been caused by infection, toxins, trauma, or metabolic disturbances, the encephalopathy shall be considered to be a condition set forth in the table." The quite different tenor and scope of the second sentence as written makes clear that the government can rely on a factor that is not one of the listed four, as long as it is possible to determine by a preponderance of the evidence that the factor identified by the government caused the encephalopathy.

Moreover, Section 300aa-13(a)(1)(B) and Section 300aa-14(b)(3)(B) are structured and operate differently. Section 300aa-14(b)(3)(B) permits the Secretary to show that the identified factors have caused the encephalopathy and that therefore the encephalopathy is not a Table condition in the first place. Section 300aa-13(a)(1), on the other hand, permits the Secretary to show that, even though the claimant *has* made a prima facie showing of a Table injury, "factors unrelated" to administration of the vaccine actually caused the child's condition. Thus, even assuming that the Secretary were limited to the factors identified in Section 300aa-14(b)(3)(B) in showing that an encephalopathy is not a Table condition, the plain language of Section 300aa-13(a)(1) would still permit the Secretary to show that other "factors unrelated" to the vaccine caused the child's condition.

The legislative history confirms that the Act was not intended to operate in a dramatically different fashion in cases of alleged encephalopathies. In explaining the provision relating to encephalopathies, the House Report states that the provision "restates in specific terms the general rule described in Section 2113." H.R. Rep. No. 908, 99th Cong., 2d Sess. Pt. 1, at 19 (1986). The language of Section 2113 referred to in the House Report is identical to the language of Section 300aa-13. H.R. Rep. No. 908, *supra*, at 51-52.

Respondents' more restrictive interpretation also makes no sense. If respondents' view were accepted, it would mean that the Secretary would be unable to rely on genetic conditions, such as Down's syndrome, to rebut a prima facie case of causation. Congress could not have intended that result.[2]

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[2] The Secretary recently issued regulations, pursuant to 42 U.S.C. 300aa-14(c), modifying the Vaccine Injury Table and the qualifications and aids to interpretation in a number of respects. 60 Fed. Reg. 7678-7696. (1995). The new regulations apply only to petitions for compensation filed after March 10, 1995. *Id.* at 7678. Accordingly, they have no application to the present case.

Among the modifications made by the new regulations are revisions to the qualifications and aids to interpretation of the Table with respect to encephalopathy. Under the regulations, a vaccine recipient will be considered to have suffered an encephalopathy "only if such recipient manifests, within the applicable period, an injury meeting the description * * * of an acute encephalopathy, and then a chronic encephalopathy persists in such person for more than 6 months beyond the date of vaccination." 42 C.F.R. 100.3(b)(2). An acute encephalopathy "is one that is sufficiently severe so as to require hospitalization," 42 C.F.R. 100.3(b)(2)(i), and, in the case of children who are less than 18 months of age, is indicated "by a significantly decreased level of consciousness lasting for at least 24 hours," 42 C.F.R. 100.3(b)(2)(i)(A). "Seizures in themselves are not sufficient to constitute a diagnosis of encephalopathy," and in the absence of other evidence, "seizures shall not be viewed as the first symptom or manifestation of the onset of an encephalopathy." 42 C.F.R. 100.3(b)(2)(i)(E). A chronic encephalopathy occurs when "a change in mental or neurological status * * * persists for a period of at least six months." 42 C.F.R. 100.3(b)(2)(ii). When the evidence indicates that a child's chronic encephalopathy "is secondary to genetic, prenatal, or perinatal factors," or when "a preponderance of the evidence [indicates] that the encephalopathy was caused by an infection, a toxin, a metabolic disturbance, a structural lesion, a genetic disorder or trauma (without regard to whether the cause of the infection, toxin, trauma, metabolic

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For the foregoing reasons, as well as those stated in our opening brief, the judgment of the court of appeals should be reversed and the case should be remanded to the court of appeals for review of the judgment of the Court of Federal Claims under the proper legal standards.

Respectfully submitted.

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disturbance, structural lesion or genetic disorder is known)," the encephalopathy is not considered a Table condition. 42 C.F.R. 100.3(b)(2)(ii) and (iii).

The regulations also remove residual seizure disorder from the list of conditions associated with the DPT vaccine. 42 C.F.R. 100.3(a).